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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/849,683	-	05/04/2001	Rebanta Bandyopadhyay	3479	8928	
26648	7590	02/09/2005		EXAM	INER	
		RPORATION	,	JONES, DV	JONES, DWAYNE C	
GLOBAL F		DEPARTMENT 1027		ART UNIT	PAPER NUMBER	
ST. LOUIS, MO 63006				1614		

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/849,683	BANDYOPADHYAY ET AL.
Office Action Summary	Examiner	Art Unit
	Dwayne C Jones	1614
The MAILING DATE of this communic Period for Reply	ation appears on the cover sheet wi	th the correspondence address
A SHORTENED STATUTORY PERIOD FOTHE MAILING DATE OF THIS COMMUNION. Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30). If NO period for reply is specified above, the maximum states a Failure to reply within the set or extended period for reply within the set or extended period for reply wany reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).	CATION. of 37 CFR 1.136(a). In no event, however, may a respective. days, a reply within the statutory minimum of thirty utory period will apply and will expire SIX (6) MON will, by statute, cause the application to become AB.	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed	i on <u>28 OCT 2004</u> .	
2a) ☐ This action is FINAL .	b)⊠ This action is non-final.	
3) Since this application is in condition f	or allowance except for formal matte	ers, prosecution as to the merits is
closed in accordance with the practic	e under <i>Ex parte Quayl</i> e, 1935 C.D	. 11, 453 O.G. 213.
Disposition of Claims		
4) Claim(s) <u>1,4-11 and 13-15</u> is/are pen	ding in the application.	•
4a) Of the above claim(s) is/ard	e withdrawn from consideration.	
5) Claim(s) is/are allowed.		
6) Claim(s) <u>1,4-11 and 13-15</u> is/are reje	cted.	
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restrict	ion and/or election requirement.	
Application Papers		
9) The specification is objected to by the	Examiner.	
10) The drawing(s) filed on is/are:	a) accepted or b) objected to I	by the Examiner.
Applicant may not request that any object	tion to the drawing(s) be held in abeyan	ice. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including	the correction is required if the drawing((s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to	by the Examiner. Note the attached	Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		
	documents have been received.	
	documents have been received in A	
·	of the priority documents have been	received in this National Stage
application from the Internation		
* See the attached detailed Office action	for a list of the certified copies not	received.
Attachment(s)		·
1) Notice of References Cited (PTO-892)	4) Interview S	summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (P1	rO-948) Paper No(s	s)/Mail Date
 Information Disclosure Statement(s) (PTO-1449 or F Paper No(s)/Mail Date 	PTO/SB/08) 5) Notice of In 6) Other:	nformal Patent Application (PTO-152) —·

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DETAILED ACTION

Status of Claims

- 1. Claims 1, 4-11, and 13-15 are pending.
- 2. Claims 1, 4-11, and 13-15 are rejected.
- 3. Claims 16-39 are cancelled as per the amendment of October 28, 2004.

Response to Arguments

4. Applicant's arguments with respect to claims 1, 4-11, and 13-15 have been considered but are most in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 4-11, and 13-15 under 35 U.S.C. 112, first paragraph, because the specification, is withdrawn in response to the amendment of October 28, 2004.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 9. Claims 1, 4-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stjernschantz et al. of WO 00/25771 A1 possessing a publication date of May 11, 2000. Stjernschantz et al. teach of employing COX-2 inhibitors to treat inflammatory conditions of the eye. In addition, Stjernschantz et al. teach of treating glaucoma (see page 1, lines 1-4) In particular, the prior art reference of Stjernschantz et al. specifically teach of using the COX-2 inhibitors of celecoxib, rofecoxib, and DuP 697, (see claim 7). Stjernschantz et al. also teach and provide motivation to the skilled artisan to include ophthalmologically compatible vehicles, which may be employed for preparing compositions of this invention with aqueous solutions, preservatives, polymers to increase the viscosity of the solutions, inclusion complexes. These pharmaceutically acceptable adjuvants could increase the contact time of the agent thus

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increasing its effectiveness to the eye. From these teachings, one having ordinary skill in the art would have been motivated to include other known COX-2 inhibitors for the treatment of inflammatory and painful conditions of the eye.

Obviousness-type Double Patenting

- 10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
- 11. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
- 12. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
- 13. The provisional rejection of claims 1, 4-11, and 13-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 24, 26, and 27 of copending Application No. 09/904,098 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the treatment of COX-2 mediated disorders of the eye with the administration of a selective COX-2 inhibitor.
- 14. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the <u>cited U.S.</u> patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, <u>all U.S. patents and patent application</u> publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

PRIMARY EXAMINER
Tech Ctr. 1614
February 4, 2005